

REMARKS

Applicants request entry of the Amendment and reconsideration of rejection of the claims.

Claims 1 and 20 have been amended. No new matter is added by the amendments. Support for the amendments can be found at page 10, lines 11-15 of the specification. New claim 23 has been added. Support for the new claim can be found at page 10, lines 30-35.

Claims 5-6, and 13-14 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these claims in one or more continuation applications.

Therefore, claims 1-3, 7-12, and 20-22 are pending in the application.

Petition for Extension of Time

It is noted that a three-month petition for extension of time is necessary to provide for the timeliness of the response. A request for such an extension is made extending the time for response from January 6, 2004 to April 6, 2004.

Specification

The Examiner has objected to the specification due to informalities involving hole punches at the top of pages 2-3, 5, 10, 13, and 36. Applicants have submitted with this response replacements for these pages of the specification. Marked up copies of these pages are not provided because no text has been moved or replaced. The Examiner had an objection to page holes at the top of the page. Applicants submit that the substitute pages do not raise any issues of new matter. Withdrawal of this objection is requested.

The specification was also objected to for alleged lack of proper antecedent basis. The Examiner contends that the claimed subgenus as recited in claim 20 wherein A2 and A4 are independently W or L is not supported by the application. Without acquiescing to the rejection and solely to expedite prosecution, claim 20 has been amended so that position A2 is W. This amendment is explicitly supported by the specification at page 10, line 12. The claims have been amended so that A4 is now W or L. Applicants submit that this claim is supported by the specification at page 10, lines 11 to 15. At line 12, the specification indicates A4 is W and at line 14, the specification indicates A4 may be leucine. Moreover, at page 26, Applicants have described specific embodiments; wherein A2 is W and A4 is L. At page 32, Applicants have

described specific embodiments; wherein A2 is W and A4 is L or W. Thus, Applicants submit that claim 20 is fully supported by the specification. Withdrawal of this objection to the specification is requested.

35 U.S.C. § 112, second paragraph

Claims 1-3 and 5-14 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The examiner contends that claim 1 is indefinite in reciting that the "carboxy terminus of C1 is optionally protected with a carboxy protecting group and the amino terminus of C2 is optionally protected with an amino protecting group."

Applicants have corrected this obvious typographical error by amending claim 1 to recite that "the amino terminus of C1 is optionally protected with an amino protecting group and the carboxy terminus of C2 is optionally protected with a carboxy protecting group." Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. § 102

Claims 1-2, 4, 5, 8, and 9 stand rejected under 35 U.S.C. 135 102(e) as being anticipated by Wrighton et al. et al for the reasons stated in the last Office Action. The Examiner asserts that A1 of the instant claim corresponds to X4 of Wrighton et al. which is R, H, L, or W. The Examiner contends that the subgeneric formula of Wrighton et al. with A1 defined as W, H and L together with the species included in the subgenus fully meets the claimed invention. Applicants note that claim 4 is a previously cancelled claim and claim 5 has been cancelled. With respect to the remaining claims, the rejection is respectfully traversed.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131.01, citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Independent claims 1 and 20 presently recite that A2 is amino acid W and W or L at position A4. Applicants submit that Wrighton et al. nowhere discloses a library of peptides comprising W at the position corresponding to A2 and W or L at position A4 of the present claims. Rather, in some embodiments, X5 of Wrighton et al., which corresponds to A2 of Applicants' claims, is limited to M, F, or I (See Abstract). Moreover, Wrighton et al. does not disclose an isolated library or plurality of cyclic peptides where each member has W at position A2 and a W or L at position A4. Applicants submit, therefore, that claim 1 and its dependent claims 2, 5, 8, and 9 are

patentable over Wrighton et al. under 35 U.S.C. 135 102(e) at least for this reason. Withdrawal of this rejection is respectfully requested.

35 U.S.C. § 103

Claims 1-3, 5-10, 12-14, and 20-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wrighton et al. for reasons advanced in the last Office Action. The Examiner asserts that the subgeneric formula of Wrighton et al. with A1 defined as W, H and L together with the species included in the subgenus renders the claims prima facie obvious. The Examiner asserts that one of ordinary skill could pick and choose amino acid residues from the library of Wrighton et al. to arrive at the claimed invention. Claims 5-6 and 13-14 have been cancelled. With respect to the remaining claims, Applicants respectfully traverse this rejection.

In order to establish a prima facie case of obviousness, three basic criteria must be met, namely: (1) the reference must teach or suggest all of the claim limitations; (2) there must be a suggestion or motivation, either in the reference itself or in the knowledge generally available to one of skill in the art to modify the reference; and (3) a reasonable expectation of success. Applicants submit that not all of these requirements have been met because the reference does not disclose all of the claim limitations, and there is no suggestion or motivation to modify the reference to disclose all of the claim limitations.

As stated above regarding the 102(e) rejection, independent claim 1 presently recites that A2 is amino acid W and A4 is W or L. Similarly, independent claim 20 also recites that A2 is amino acid W and A4 is W or L. Wrighton et al. does not disclose a library of peptides comprising W at the position corresponding to A2 and W or L at positions corresponding to A4 of the present claims. Rather, in some embodiments, X5 of Wrighton et al., which corresponds to A2 of Applicants' claims, specifies M, F, or I. Moreover, Wrighton et al. does not teach or suggest an isolated library or plurality of cyclic peptides with a W at position A2 and W or L at position A4. Therefore, Wrighton et al. does not teach all of the limitations of the claims.

In addition, the claims are not obvious in view of Wrighton et al. because there is no suggestion or motivation, either in Wrighton et al. itself or in the knowledge generally available to one of skill in the art, to modify the reference to have all limitations of the claims. The mere fact that a reference can be modified to obtain Applicants' invention does not render the claims obvious unless the prior art also suggests the desirability of the modification. MPEP 2143.01.

“The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done.” Id.

Applicants respectfully submit that the Examiner has not provided any reason why it would be desirable to modify the peptides disclosed in Wrighton et al. to have all limitations of the present claims. In response to Applicants' previous arguments, the Examiner simply states that “[i]t is readily apparent from the disclosure of Wrighton et al. that one having ordinary skill in the art can pick and choose amino acid residues from the library of Wrighton et al. to arrive at the instant claimed invention.” Applicants respectfully submit, however, that this statement is a mere assertion, without any supporting reasoning or evidence as required by the MPEP, that one of ordinary skill would be motivated to pick and choose the amino acid residues to modify Wrighton et al. peptides to arrive at Applicants' claimed invention. There is no direction or indication in Wrighton et al. as to which other amino acids can or should be selected at those positions from the many possibilities.

The Wrighton et al. reference is directed to identifying agonists of EPO and identifies in certain embodiments that the position corresponding to A2 of the claimed invention is substituted with M, F or I. This reference does not teach or suggest the desirability of substituting the amino acids at this position with tryptophan. Moreover, there is no discussion in Wrighton et al. of the desirability of forming a trp-trp or trp-leu cross-strand pair between A2 and A4 in order to enhance hairpin stability. The Wrighton et al. reference does not teach or suggest the ability of the cyclic peptides as claimed by Applicants to accommodate a number of different types of turn structures or that the stability of the turn sequences would be enhanced.

Thus, Applicants submit that Wrighton et al. reference does not teach or suggest all of the elements of Applicants' claims and provides no motivation or suggestion to modify the peptides to the presently claimed library or plurality of peptides. Applicants, therefore request withdrawal of the rejection on this basis.

Claims 1-3, 5-10, 12-14, and 20-22 were rejected under 35 U.S.C. § 103(a) as unpatentable over McLafferty et al. The Examiner contends that the phage library disclosed in Table 1 of McLafferty renders the present claims obvious. Specifically, the Examiner asserts that the use of the word “comprising” in the present claims does not preclude the presence of other amino acid residues in the prior art such as insertions, deletions, and substitutions. Claims 5-6 and 13-14 have been cancelled. With respect to the remaining claims, the rejection is respectfully traversed.

While Applicants do not agree with the Examiner's interpretation of "comprising" as used in the claims, Applicants have amended the independent claims 1 and 20 solely to further prosecution of the case. These claims now recite cyclic peptides having an amino acid sequence of C1-A1-A2-(A3)_n-A4-A5-C2 [SEQ ID NO:1]. Applicants submit that McLafferty et al. nowhere teaches or suggests peptides having this amino acid sequence. Withdrawal of the rejection of claims 1-3, 5-10, 12, and 20-22 over McLafferty is therefore respectfully requested.

Summary

Applicants submit that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative if prosecution may be assisted thereby.

Respectfully submitted,

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